(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
3 May 2001 (03.05.2001)

PCT

(10) International Publication Number
WO 01/30254 A1

(51) International Patent Classification[7]: A61B 19/00

(21) International Application Number: PCT/CA00/01245

(22) International Filing Date: 26 October 2000 (26.10.2000)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
09/426,763 26 October 1999 (26.10.1999) US

(63) Related by continuation (CON) or continuation-in-part (CIP) to earlier application:
US 09/426,763 (CIP)
Filed on 26 October 1999 (26.10.1999)

(71) Applicant *(for all designated States except US)*: **CEDARA SOFTWARE CORP.** [CA/CA]; 6509 Airport Road, Mississauga, Ontario L4V 1S7 (CA).

(72) Inventor; and
(75) Inventor/Applicant *(for US only)*: **MENHARDT, Wido** [CA/US]; 17706 Blackberry Hill Road, Los Gatos, CA 95030 (US).

(74) Agents: **ORANGE, John, R., S.** et al.; Orange & Chari, Suite 4900, P.O. Box 190, Toronto Dominion Bank Tower, Toronto, Ontario M5K 1H6 (CA).

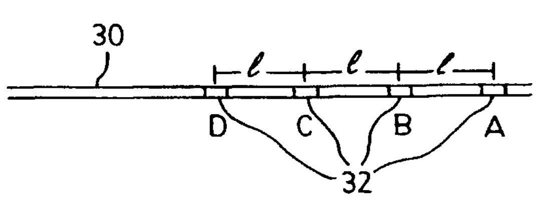
(81) Designated States *(national)*: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, HR, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published:
— *With international search report.*
— *Before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments.*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: CATHETER WITH RADIOPAQUE MARKERS FOR 3D POSITION TRACKING



(57) Abstract: A probe and a method for tracking the probe. A catheter comprising a plurality of radiopaque markers arranged at predetermined distances along a length of the catheter, and at an operational end of the catheter, the markers having no allowable mirror symmetries except with respect to planes orthogonal to a longitudinal axis of the catheter such that an orientation of the catheter relative to a plane is determined by using a projection of an image of the marker onto the plane. The method for determining the position of the catheter uses the projected distance between a pair of markers on the catheter, the projected shape of at least one of the pair of markers and known position on the organ to compute the position of the markers relative to the known position whereby only a single plane projection of the markers is needed to determine the position of the catheter in the organ.

WO 01/30254 A1

CATHETER WITH RADIOPAQUE MARKERS FOR 3D POSITION TRACKING

The present invention relates to a method and system for tracking a probe.

BACKGROUND OF THE INVENTION

A number of interventional clinical procedures use medical imaging systems such as Computer Tomography (CT), Magnetic Resonance (MR), X-ray and fluoroscopy for therapeutic as well as diagnostic purposes. In some interventional procedures, a physician wishes to guide a catheter to a remote site within the body for the purpose of making measurements, retrieving samples (biopsy), effecting therapeutic actions (for example, angioplasty of an artery wall), or blocking of an artery feeding a tumor (embolization). Such catheters may be used for these procedures in place of traditional invasive surgery. The catheter is a thin tube of approximately 2-6 mm in diameter and in the order of 1 meter long. The catheter contains a number of interior passages (depending on its design) and is guided by a flexible, removable, X-ray opaque internal guide wire.

Thus a common application of X-ray fluoroscopy is in monitoring the location of the catheter inside a body. Reliable and fast determination of the tip location from the fluoro images using the digital image processing technique is required. During a fluoroscopic procedure X-rays are passed through a patient and an image is projected onto a plane, which is converted into a viewed image. Typically, the images are formed at a rate of 30 per second and displayed on a TV-like monitor.

In X-ray fluoroscopy and angiography, catheters are viewed in single or dual projections. Dual projections allow for determination of the location of the catheter in space through standard triangulation from the X-ray projections. Some systems track the position of the catheter using electromagnetic or ultrasonic position sensing technology.

In U.S. Patent No. 5,289,373 a digitizer is connected to the video output of a fluoroscope. The digitized fluoroscopic images are processed in an image-processing computer to create an enhanced image with a 2D model of a catheter in a patient being

imaged. The system includes a combinor which is a video circuit which provides a live image output monitor with either a standard video output signal from the fluoroscope or a signal that combines the standard video output signal with the enhanced digital output corresponding to the location of the catheter as determined in the image processing computer. The resulting video display is a standard fluoroscope image with an enhanced image of a catheter superimposed thereon. A major benefit of the 5,289,373 patent is that a lower dose of X-rays can be used since the radiologist can work with a "poorer" image.

In U.S. Patent 5,369,678 a method for tracking a catheter probe during a fluoroscopic procedure is described, in which a filter member is used to attenuate X-ray radiation in areas of the field of view outside the primary area of interest. Once again this patent also attempts to reduce the chance of overexposure to both the patient and physician. In U.S. Patent 5,606,981 a catheter guidewire with radiopaque markers is described such that the arrangement and opacity of the markers provide a visible referefice length that would enable the physician to make in vivo measurements of a lesion to determine its length and shape and dimensions of the artery adjacent to the lesion. In U.S. Patent No. 5,771,895, a technique for obtaining a 3D reconstruction of a vascular lumen and wall is described. The technique employs X-ray angiography in combination with intravascular ultrasound. A 3-D path of the catheter axis is reconstructed from two X-ray images, after which the stack of ultrasound contours is wrapped around this 3D-catheter centerline. In order to establish the correct rotational position of the stack around the centerline, use is made of "landmarks" or catheter features which are visible in angiograms, as well as in a simulation of these angiograms derived from the reconstructed 3D contour.

As may be seen the current approach to obtain a proper 3D reconstruction of a catheter during fluoroscopy is to use a biplane X-ray to determine a series of discrete positions of its 3D path.

It would be an advantage to provide a system and method that uses a single plane projection to obtain a 3D reconstruction of a catheter 3D path.

SUMMARY OF THE INVENTION

In accordance with a first aspect of the invention there is provided a probe comprising: a plurality of discernable markers arranged at predetermined distances along a length of the probe, the discernable markers are of a predetermined shape. An orientation of the prove relative to a plane in a coordinate system is determined by using a projection of an image of at least one of the discernable markers onto the plane.

In accordance with a further embodiment of the invention there is provided a method for determining a spatial position of a probe in a coordinate system the method comprising the steps of.

A method for determining a spatial position of a probe in a coordinate system, the method comprising the steps of:

a) selecting said probe having a plurality of discernable markers arranged at predetermined distances along a length of said probe, at least one of the discernable markers having an irregular shape to allow the determination of a spatial orientation of the irregularly shaped marker in said coordinate system;

b) projecting an image of said discernable markers onto a plane of said coordinate system;

c) using the projected distance between a pair of the discernable markers, the projected shape of said irregularly shaped marker, and a known position in said coordinate to compute the spatial position
of said discernable markers relative to said known position;

d) whereby only a single plane projection of said discernable markers is used to determine said spatial position of said probe in said coordinate system.

Thus an advantage of the invention is to provide a method and apparatus for the deten-nination of the position of an instrument relative to a known position by using, a projection of the instrument on a single plane.

BRIEF DESCRIPTION OF THE DRAWINGS

These and other features of the preferred embodiments of the invention will become more apparent in the following detailed description in which reference is made to the appended drawings wherein:

Figure 1 is a schematic diagram of a system according to an embodiment of the present invention;

Figure 2 is a schematic diagram of a catheter according to the present invention;

Figure 3 is a schematic diagram of an image display;

Figure 4 is a schematic diagram of a coordinate system for use in the present invention;

Figure 5 is a schematic, diagram of a marker according to an embodiment of the invention; and

Figures 6(a-1) are schematic diagrams of various projections of the marker in figure 5.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

In the following description, like numerals refer to like structures in the drawings. Referring to figure 1, system for tracking a catheter in accordance with a generalized embodiment of the present invention is indicated generally at numeral 10. The location of a catheter 12 to be tracked in an organ 14 is shown positioned between an X-ray source 16 and an image detection screen or fluoroscope 18. The output from the fluoroscope is passed through a processing system 20 before being generated on a display monitor 22 or stored in memory for future display. The present invention provides an improved catheter and an image processing system for tracking the position of the catheter using a single X-ray projection. Referring to figure 2, the catheter 30 is shown having a series of radiopaque markers 32 positioned at a known distance, *l*, apart. Typically, these markers are positioned at equal distances along the catheter (but non-equal distances could also be used).

Referring to figure 3 an X-ray projection of the catheter 30 on an image display is shown by numeral 40. The user (typically a cardiologist) has to mark a known location in the X-ray projection. This would typically be an anatomical reference such as the point where the

catheter enters the organ which, in this example, is the heart. For example as shown in figure 3, a known identifiable point X, the aorta opening of the heart 46 in this embodiment is used as the reference location. The method allows for the determination of the catheter tip in relation to this anatomical reference X based on a dead reckoning procedure from marking A to marking B, C, D and so forth on the catheter. This method is based on two known characteristics of the catheter 30, the distances l between the markings, and the shapes of the markings A, B, C, D and so forth.

The use of the first characteristic of the catheter, that is the markings will be discussed first with reference to Figure 4. As shown schematically in figure 4, a projection of a single pair of markers A and B is shown on the image plane 40, having orthogonal axes x and y in the plane. It is also assumed for convenience that the marker A is in the image plane, however generally A is in a plane parallel to the image plane 40. An algorithm in the processing system 20 utilizes the projected distances l' between markers on image plane 40 and the actual distance l between the markers (A and B as exemplified) to compute the distance l_z, orthogonal to the image plane 40. The distances of the markings along the catheter will be known. Normally, they would be equidistant, for example, every 5 mm. Since the distance between two markings l is known, the distance l' of the markings in the X-ray projection 40 allows one to calculate the distance of one of the markers (B in this example) in the direction orthogonal (z-axis) to the projection plane 40. The calculation may be done using simple triangulation. It may be remembered that the relative distance of A and B is computed. That is since the distance of A to the image plane is zero, as it is assumed A to be in the plane, the distance l, is both the projection of the distance of B to the image plane onto the z axis and the projection of the distance A-B onto the z axis.

The above calculation leaves the question as to which direction 54 or 56 relative to the image plane 40 the marker B projects ambiguous. That is, the catheter 30 may be projecting in space in a direction into or out-of the image plane 40.

Accordingly a further feature of the present invention provides for the use of a second characteristic of the catheter. The radiopaque markers 32 are preferably selected to be of a predetermined shape. The shape of the markers 32 is selected to allow the determination of

the orientation of the marking in space from the projection on the image plane 40. Hence, the shape, preferably irregular. of the markers when applied to the catheter should have no allowable mirror symmetries except with respect to planes orthogonal to the axis of the catheter (otherwise multiple orientations could result in identical projections). Based on the orientation, it is possible to determine which of two markings is closer to the X-ray projection plane.

The method employs this principle for each pair of markings. Starting at a marking at the tip of the catheter, the relative position of each pair of markings is accumulated until the anatomical reference point (marked by the user) is reached. The accumulated relative positions then give the relative position of the catheter tip.

Alternatively, the position of the tip of the catheter may be determined relative to a known position by moving from the position of marker closest to the known anatomical position and moving toward the tip.

The catheter markings have to be easily visible or discernable in the X-ray projection; hence they have to be radio-opaque. The markings typically should not obstruct the internal diameter of the catheter (e.g., wires), hence they are preferably parts of a hollow cylinder. And the markings have to have no allowable mirror symmetries (with the exception of planes orthogonal to the axis of the catheter). It is recognized that many such shapes are possible other than what is shown.

Referring now to figure 5, three projections of a radio-opaque marker according to an embodiment of the present invention is shown generally by numeral 60. The marker 60 has the shape of a right angle triangle. The marker has only one mirror symmetry along an axis A'. The marker 60 is attached to the outer surface of the catheter 32 so that a base of the triangle is orthogonal to the longitudinal axis A' of the catheter body. The length of this base is chosen so that when wrapped around the catheter it does not overlap and is preferably of length half the circumference of the catheter.

The use of the method of this invention will be described with reference to the coordinate system S as defined in figure 4, where the x-y plane is parallel to the projection plane of the X-ray projection, and where the origin P_{ref} = (X=O; Y=O; z=O) is at the anatomical reference location determined by the user (for example, the point where the catheter enters the heart).

Next, a coordinate system S' is defined which is axioparallel to S, but where the origin coincides with the catheter tip p_o = (x_o'=O; y_o'=O; z_o'=O) as shown in figure 4. In a first approximation, the catheter is assumed to consist of a set of fixed links (between the markings) and completely free rotation points where the links meet (at the markings). Corrections to this approximation are discussed later. The description of the method is based on equidistant markings along the catheter, spaced by a distance *1*.

The first marking after the catheter tip is at location p_1 = (x_1', y_1', z_1'). The distance between p_0 and p_1, in 3-space is equal to *1*.

From the X-ray projection x_1', y_1' are known, and the catheter tip is defined to be the origin of S' with p_o = (x_o'=O;y_o'=O;z_o'=O). Using the Pythagorean theorem then yields |**z₁'** |

The sign of z_1' is determined based on the orientation of the marker at the catheter tip. If the marker indicates that the catheter tip is directed towards the positive z' axis, then z_1' will be z_1' = -|**z_1'** |. Otherwise, z_1' = |**z_1'** |. At this point, the coordinates of p_1 are known in the S' coordinate system.

This method is repeated for each pair of markings, until the anatomical reference point P_{ref} is reached. P_{ref} is now known in the coordinate system S' (which is defined by the catheter tip p_o as origin). Therefore, since the position of the catheter tip is known in S', and the P_{ref} is known is both S' and S, the position of the catheter tip can be determined in coordinate system S.

Referring to figures 6(a) to 6(l) the various orientations of the marker as projected onto the image plane is shown, assuming that the plane of the drawing sheet is the plane of

the image plane 40. As may be seen in figures 6(a-d), the projected shapes of the marker are shown if the catheter is tilted to the right, that is, the catheter is exiting the rear of image plane at the right hand side. In figures 6(e-h), the projected shapes of the marker are shown if the catheter is rotated about its axis. In figures 6(1-I), the projected shapes of the marker are shown if the catheter is tilted to the left, that is, the catheter is exiting the rear of image plane at the left hand side.

The validity of the assumption of fixed links joined at the locations of the markings obviously depends on the characteristics of the catheter, and the distances between the links. Depending on these characteristics, the orientation of several neighboring markers may have to be used to determine whether the z'-distance between two subsequent markers is positive or negative.

The assumption of fixed links will yield an approximation of the position of the catheter tip p_o in reference to the anatomical reference point $P_{ref.}$ Using more sophisticated models for the catheter, modeling its flexibility and curvature can refine this assumption. None of these refinements modify the principle of dead reckoning described above.

The method described above assumes parallel projection, however X-ray projections from a single source follow cone-beam geometry. This can be taken into account through an iterative refinement process (for example, by adjusting the first approximation results for cone beam geometry, and comparing the results of a simulated projection with the actual X-ray projection). Corrections to other imaging artifacts and distortions (such as pincushion distortions) can be addressed in a similar manner.

This method is described for applications of catheter tip position determination in X-ray projections (fluoroscopy and angiography). However, the method can be extended into other application areas with similar requirements and characteristics. Specifically, the method is not limited to catheters (other probes similar to catheters, tubes, linked links, etc. could be used), and it is not limited to X-ray projections (for example, visible light projections could be used with corresponding discernable markers responsive thereto). As may be seen the method of the present invention may be implemented in software for execution by the

processor 20. Further method of this invention although described with reference to medical applications such as angiography, linear ablation and such like may equally well be applied to other applications such as tracking the position of probes in pipes and such like.

Furthermore, the classification of the projections shown in figure 6 may be accomplished by known pattern recognition software.

Although the invention has been described with reference to certain specific embodiments, various modifications thereof will be apparent to those skilled in the art without departing from the spirit and scope of the invention as outlined in the claims appended hereto.

THE EMBODIMENTS OF THE INVENTION IN WHICH AN EXCLUSIVE PROPERTY OR PRIVILEGE IS CLAIMED ARE DEFINED AS FOLLOWS:

1. A probe comprising:

a) a plurality of discernable markers locatable at predetermined distances along a length of said probe,

b) the discernable markers are of a predetermined shape,

c) wherein an orientation of said probe relative to a plane in a coordinate system is determined by using a projection of an image of at least one of said discernable markers onto said plane.

2. The probe according to claim 1 further comprising one of said plurality of discernable markers is locatable at an operational end of said probe.

3. The probe according to claim 1 further comprising said at least one of said discernable markers having an irregular shape to allow the determination of an spatial orientation of said at least one of said discernable markers in said coordinate system.

4. The probe according to claim 3, wherein said at least one of said discernable markers is of a symmetrical shape with respect to an orthogonal plane to a longitudinal axis of said probe.

5. The probe according to claim 3, wherein said discernable markers are connectable adjacent to an exterior surface of said probe.

6. The probe according to claim 5, wherein said least one of said discernable markers has a base locatable orthogonal to a longitudinal axis of said probe.

7. The probe according to claim 3, wherein said irregular shape is triangular.

8. The probe according to claim 6, wherein said base does not overlap when said at least one of said discernable markers is located about a cross sectional perimeter of said probe.

9. The probe according to claim 3, wherein said discernable markers are radiopaque markers discernable using an X-ray projection.

10. A method for determining a spatial position of a probe in a coordinate system, the method comprising the steps of

a)selecting said probe having a plurality of discernable markers arranged at predetermined dista

b)projecting an image of said discernable markers onto a plane of said coordinate system;

c)using the projected distance between a pair of the discernable markers, the projected shape of of said discernable markers relative to said known position;

d) whereby only a single plane projection of said discernable markers is used to determine said spatial position of said probe in said coordinate system.

11. The method as defined in claim 10 further including the step of: determining for each pair of said discernable markers a relative distance between said pair in a direction orthogonal to said plane; and using said projected shape of one said pair to determine a direction of said distance relative to said plane.

12. The method as defined in claim 10, wherein said at least one of said discernable markers having a planar shape of a right angle triangle.

13. The method as defined in claim 10, wherein said discernable markers are spaced at equal distances along said probe.

14. The method as defined in claim 10 further including the steps of:

a) determining a reference point in said coordinate system;

b) determining a location of said probe tip relative to said plane;

c) determining a position of each of said discernable markers relative to said tip;

and

d) computing said spatial position of said tip relative to said reference point.

15. The method according to claim 10, wherein said discernable markers are radiopaque markers discernable using an X-ray projection.

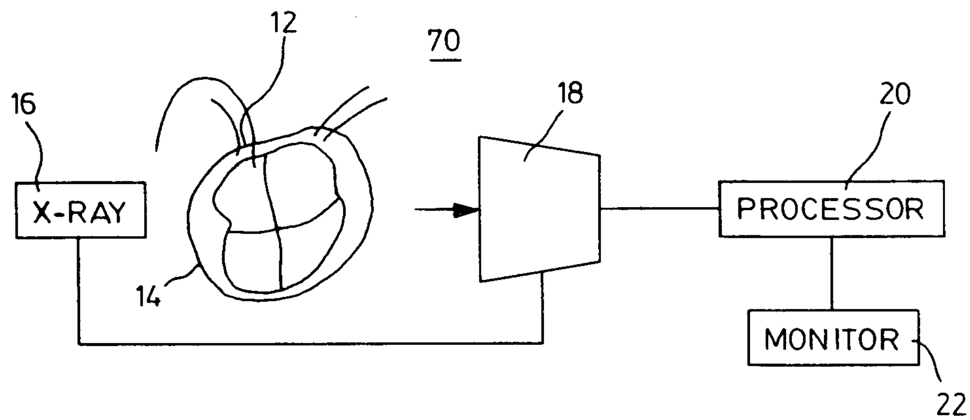


FIG. 1

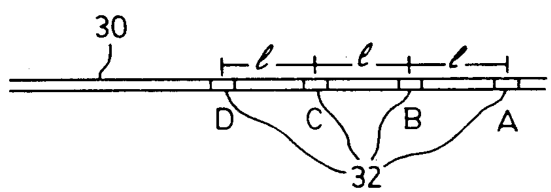


FIG. 2

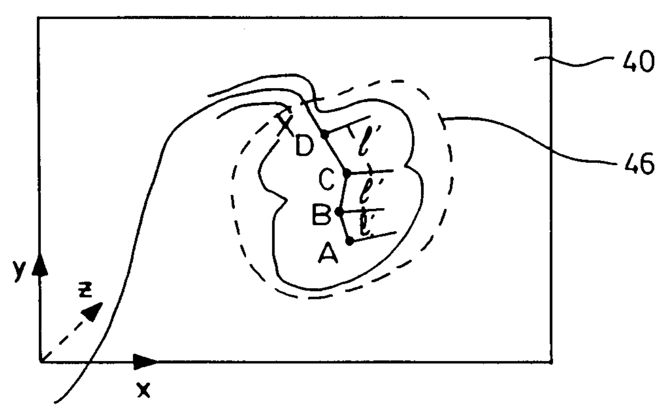


FIG. 3

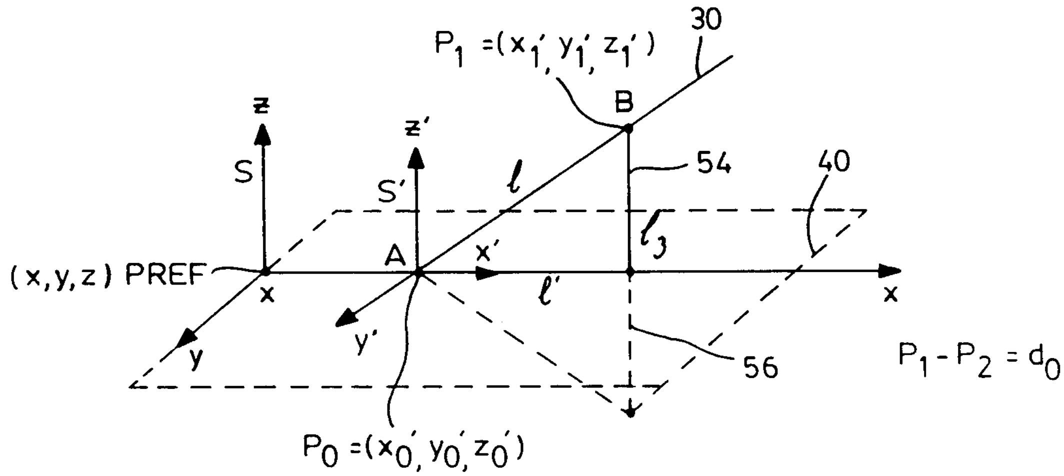

30
$P_1 = (x_1', y_1', z_1')$
B
z
z'
S
S'
54
40
ℓ
ℓ_3
(x,y,z) PREF
x
A
x'
ℓ'
x
y
y'
56
$P_1 - P_2 = d_0$
$P_0 = (x_0', y_0', z_0')$

FIG. 4

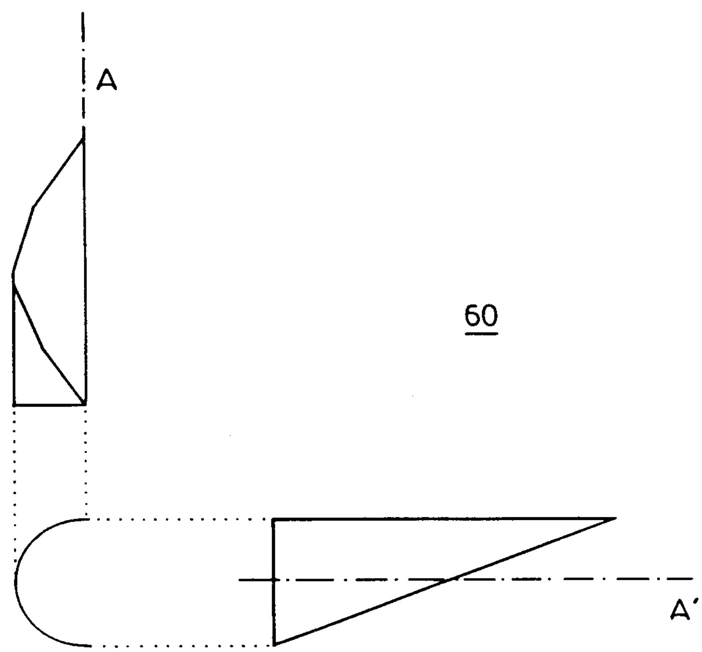

A
60
A'

FIG. 5

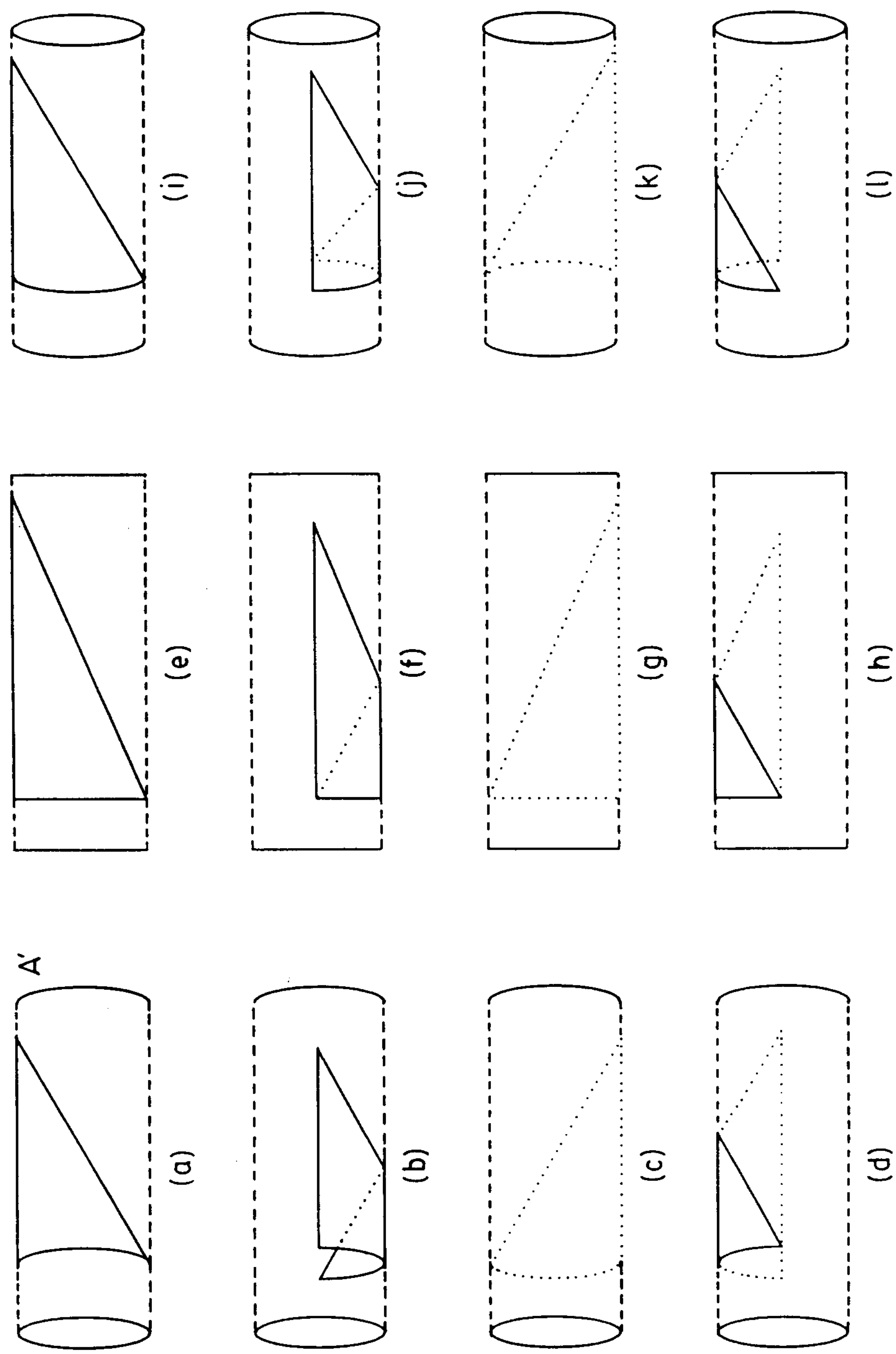


FIG. 6

INTERNATIONAL SEARCH REPORT

International Application No
PCT/CA 00/01245

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B19/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B G06T

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y A	EP 0 244 818 A (TERUMO CORP) 11 November 1987 (1987-11-11) column 4, line 21 - line 35; figures 2,5	1-6,8,9 7 10
Y	DE 38 33 365 A (BIOTRONIK MESS & THERAPIEG) 6 April 1989 (1989-04-06) column 5, line 26 - line 36; figure 4	7
A	US 5 835 563 A (BANI-HASHEMI ALI REZA ET AL) 10 November 1998 (1998-11-10) abstract; figure 3	1,10

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
6 March 2001	13/03/2001

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Mayer, E

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/CA 00/01245

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 0244818 A	11-11-1987	JP 1664398 C	19-05-1992
		JP 3031063 B	02-05-1991
		JP 62261371 A	13-11-1987
		AU 7267087 A	17-12-1987
		DE 3750239 D	25-08-1994
		DE 3750239 T	15-12-1994
DE 3833365 A	06-04-1989	NONE	
US 5835563 A	10-11-1998	NONE	